

REMARKS

Applicants request entry of the amendments. After entry of the amendments, claims 54, 56, 58, 60, 63, 65 and 67-76 are withdrawn and claims 50, 55, 57, 59, 61, 62, 64, 66 and 77-84 are pending. Provision for extension of

5 time accompanies this paper.

To respond to the restriction requirement, Applicants have amended independent claim 50 to recite compounds where R<sup>9</sup> is -CHR<sup>10</sup>- or -CHR<sup>10</sup>-CHR<sup>10</sup>- . Applicants request a list of inventions that the Office believes is present so that they can consider filing one or more divisional applications.

10 The amendments of paragraph 1 updates the cross reference to priority applications and corrects the designation of a priority application from a divisional to a continuation. The amendment of specification paragraph 697 beginning at page 239 replaces the diagrams (at pages 241-244) in the specification with tables containing the data originally present in the diagrams. Amendments of  
15 other paragraphs in the specification correct typographical errors. These amendments introduce no new matter.

The Office's attention is directed to commonly owned copending U.S. patent application serial Nos. 10/651,515, 10/526,321, 10/728,400, 10/319,356, 10/329,065, 10/602,330, 10/606,524, 10/607,415, 10/741,929, 10/876,957,  
20 10/890,490, 10/949,694, 10/949,782, 09/820,483, 10/877,911, 10/087,929, 11/234,675 and 11/241,678. Some of these applications are discussed below with regard to double patenting issues.

DOUBLE PATENTING

25 Under the judicially created doctrine of obviousness-type double patenting the Office provisionally rejected (1) claims 50, 57, 61 and 62 over claims of copending application No. 10/607,415, (2) claims 50, 55, 57, 59, 61, 62, 64 and 66 over claims of copending application No. 10/728,400 and (3) claims 50, 57, 61, 62 and 66 over claims of copending application No. 10/949,782. Applicants  
30 request the Office to hold these provisional rejections in abeyance until patentable subject matter is identified in this application or in one of the cited

copending applications. When patentable subject matter is identified in any of these applications, Applicants will evaluate the filing of a terminal disclaimer or take other action that may be appropriate at that time.

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35 U.S.C. § 103(a)

The Office maintained the rejection of claims 50, 55, 57 and 59 as allegedly obvious in view of U.S. patent 5,532,230, hereafter the '230 patent. Applicants traverse the rejection.

A determination of obviousness under 35 USC § 103(a) is determined on 10 a case-by-case basis to account for facts or situations that are unique to each case. The court has observed that "reliance on *per se* rules of obviousness is legally incorrect . . ." *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995). There are no, and there cannot be any, *per se* rules in obviousness 15 cases. *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995). With regard to a prior art chemical genus and a single chemical species, the court observed that the "fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious. *In re Jones*, 958 F.2d 347, 350, 21 U.S.P.Q.2D (BNA) 1941, 1943 (Fed. Cir. 1992)". *In re Baird*, 29 USPQ2d 1550 1994.

20 Similarly, the Board of Patent Appeals and Interferences (B.P.A.I.) stated: "In genus-subgenus or genus-species situations, one must start with the proposition that a prior art genus may or may not render a claimed subgenus or species obvious. A claimed subgenus or species, fully embraced by a prior art genus, may be unpatentable under 35 U.S.C. § 103. *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989) (compounds were obvious even though reference described 1200 compounds); *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971) (where claimed invention is subgenus of genus disclosed in prior art, the claimed invention may be *prima facie* obvious). On the other hand, the subgenus may be patentable. *In re Baird*, *supra*, 30 16 F.3d at 382, 29 USPQ2d at 1552 (Fed. Cir. 1994) (fact that claimed compound may be encompassed by a disclosed generic formula does not by

itself render that compound obvious--involving compositions containing bisphenols). However, each case must be decided on its unique set of facts. There are no, and there cannot be any, *per se* rules in obviousness cases. *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995)." *S.L. Palackal et al., v. L. Resconi et al.*, 2000 Pat. App. Lexis 1 (P.B.A.I. 2000).

5 Obviousness rests on several factual underpinnings: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of skill in the art, and (4) the objective indicia of nonobviousness. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566-67, 1  
10 U.S.P.Q.2D (BNA) 1593, 1595-96 (Fed. Cir. 1987); *Graham v. John Deere Co.*,  
383 U.S. 1, 17, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966). To establish a case of  
prima facie obviousness under § 103, consideration of whether the prior art  
would have suggested to those of ordinary skill in the art that they should make  
the claimed composition or device, or carry out the claimed process; and whether  
15 the prior art would also have revealed that in so making or carrying out, those of  
ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947  
F.2d 488, 493 (Fed. Cir. 1991), *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed.  
Cir. 1988). The court has observed that obviousness under 35 U.S.C. 103(a)  
requires that both "the suggestion and the reasonable expectation of success  
20 must be founded in the prior art, not in the applicant's disclosure." citing *In re*  
*Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d  
469, 473 (Fed. Cir. 1988)). *Velander v. Garner*, 348 F.3d 1359; 2003 U.S. App.  
LEXIS 22717; 68 USPQ2D (BNA) 1769 (Fed. Cir. 2003).

25 In establishing obviousness, the determination must involve more than  
indiscriminately combining prior art. *Micro Chem., Inc. v. Great Plains Chem. Co.*,  
103 F.3d 1538, 1546 (Fed. Cir. 1997). To avoid impermissible hindsight-based  
obviousness analysis, one must rigorously apply the requirement for a showing  
of a teaching or motivation to combine prior art references. *Ecolochem, Inc. v.*  
*Southern Cal. Edison Co.*, 227 F.3d 1361, 1372 (Fed. Cir. 2000) (citing *In re*  
30 *Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999), abrogated on other grounds by  
*In re Gartside*, 203 F.3d 1305 (Fed. Cir. 2000)). To avoid the subtle but powerful

attraction of a hindsight-based obviousness analysis, it is necessary to rigorously apply the requirement for a showing that the teaching or motivation to combine prior art references is in those references and not in the patent applicant's own disclosure. *In re Dembiczak, supra*.

5        In explaining the underpinnings of a finding of obviousness, the court has observed that the "need for specificity pervades this authority. See, e.g., *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2D (BNA) 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for  
10 combination in the manner claimed"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998) ("even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been  
15 motivated to select the references and to combine them to render the claimed invention obvious."); *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (the examiner can satisfy the burden of showing obviousness of the combination "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art  
20 would lead that individual to combine the relevant teachings of the references")."  
*In re Lee*, 277 F3d 1338; 61 USPQ2D (BNA) 1430 (Fed. Cir. 2002).

      In considering the content of a prior art reference, the P.B.A.I. observed: "A *prima facie* case of obviousness is established when the teachings of the prior art itself would appear to have suggested the claimed subject matter to one of ordinary skill in the art (see *In re Bell*, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993)). . . . . Insofar as the references themselves are concerned, we are bound to consider the disclosure of each for what it fairly teaches one of ordinary skill in the art, including not only the specific teachings, but also the inferences which one of ordinary skill in the art would reasonably  
25 have been expected to draw therefrom (see *In re Boe*, 355 F.2d 961, 965, 148 USPQ 507, 510 (CCPA 1966) and *In re Preda*, 401 F.2d 825, 826, 159 USPQ  
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342, 344 (CCPA 1968))." *Ex parte NYLEN*, 2003 Pat. App. LEXIS 35 (B.P.A.I., 2003).

With regard to evidence to refute obviousness, the court has observed that "unexpected superior properties from an invention support the conclusion that the invention was not obvious to one of ordinary skill in the art. *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991); *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). As the Federal Circuit has recognized, the reason behind this principle is "that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." *In re Mayne*, 104 F.3d 1339, 1343 (Fed. Cir. 1997) (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995))." *Eli Lilly and Co. et al., vs. Zenith Goldline Pharmaceuticals, Inc., et al.* 364 F Supp. 2d 820; 2005 US Dist LEXIS 64482005 U.S. Dist. LEXIS 6448 (S. IN D.C. 2005).

As noted above, a prior genus does not necessarily render later species or subgenera obvious. *Merck & Co., Inc. v. Biocraft Laboratories, Inc, supra*; *In re Baird, supra*. Because of this, the '230 patent itself must suggest the modifications needed to arrive at the presently claimed compounds. The '230 patent does not do this. The Office's attention is directed to the declaration by Dr. Reading that accompanies this paper. As stated by Dr. Reading, the '230 patent does not teach or suggest the use of any of the presently claimed compounds for treating inflammation or atopic asthma. Nor does the '230 patent provide a basis for one of ordinary skill in the art to have a reasonable expectation that the presently claimed compounds could successfully be used to treat inflammation or atopic asthma. Without the suggestion in the '230 patent itself to consider the use of the presently claimed compounds, the rejection is based on hindsight reconstruction using Applicant's claims. This is impermissible. *Ecolochem, Inc. v. Southern Cal. Edison Co, supra*; *In re Dembicza*, *supra*. Also, without a basis for one of ordinary skill in the art to have a reasonable expectation of success, the rejection is improper. *In re Vaeck, supra*; *In re Dow Chem. Co., supra*; *Velander v. Garner, supra*.

In addition to these considerations, the declaration by Dr. Reading describes unexpected properties for use of exemplified compounds in treating inflammation. Such properties are evidence that the claimed compounds would not have been obvious to one of ordinary skill in the art. *In re Baxter Travenol*

5 *Labs., supra.*

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

Respectfully submitted,

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